Applicant
 :
 Lars Tommy Westbye, et al.

 Appl. No.
 :
 10/626/218

 Examiner
 :
 Catherine Witczak

 Docket No.
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 706/337,4003

## Amendments to the Claims

This listing of claims will replace all prior versions and listings of claims in the application:

(currently amended) A medical injection system, comprising:
 a needle guard, comprising:

a cartridge housing coupled with a release mechanism and configured to house a pre-filled medical cartridge comprising a needle located on a distal end, a plunger and a carrier configured to carry a dose;

a shield having an open proximal end and an open distal end, the shield coupled with the cartridge housing and the release mechanism and configured to extend between a retracted and an extended position that substantially covers the needle when the cartridge is housed in the cartridge housing, wherein the release mechanism is configured to maintain the shield in the retracted position and allow the shield to extend upon engagement of the release mechanism; and

an automatic injection system configured to house the needle guard and the medical cartridge and configured to inject the dose when activated, the automatic injection system comprising:

a drive system configured to depress the plunger and engage the release mechanism when the automatic injection system is activated; and an activation system configured to activate the automatic injection system;

wherein the needle guard is removable from the automatic injection system with the shield in the extended position after injection of the dose.

2. (original) The system of claim 1, wherein the release mechanism comprises a first cooperating catch formed in the shield and a second cooperating catch formed in the cartridge housing, wherein the cooperating catches are configured to engage one another when the shield is in the retracted position and to disengage one another when the release mechanism is engaged when the shield is in the retracted position.

Applicant : Lars Tommy Westbye, et al. Appl. No. : 10/626,218

 (original) The system of claim 2, wherein the release mechanism further comprises a latch member extending proximally from the proximal end of one of the shield and the cartridge housing, the latch member being deflectable for disengaging the cooperating catches.

- (original) The system of claim 3, wherein the latch member is deflectable upon depression of the plunger.
- 5. (original) The system of claim 1, wherein the medical cartridge is insertable into the cartridge housing such that the needle extends from the distal end of the cartridge housing and the plunger extends from the proximal end of the housing and the carrier is housed therebetween.
- (original) The system of claim 5, further comprising a retainment device at the proximal end of the cartridge housing configured to secure the carrier in the cartridge housing.
- (original) The system of claim 1, wherein the shield is configured to lock in the extended position.
- (original) The system of claim 1, further comprising a shield bias member configured to apply pressure to the shield to extend the shield.
- 9. (original) The system of claim 7, wherein the release mechanism is configured to release the shield from the retracted position while the needle is exposed from the distal end of the shield and the plunger is exposed from the proximal end of the shield, and wherein the plunger remains depressible such that substantially the entire dose is injectable upon depression of the plunger.
- (original) The system of claim 1, wherein the automatic injection system further comprises:

a distal housing having an open proximal end and an open distal end, wherein the dose is injected from the distal end of the distal housing; and

a proximal housing having an open distal end and coupled with the drive system, wherein

Applicant : Lars Tommy Westbye, et al. Appl. No. : 10/626,218

Appl. No. : 10/626,218

Examiner : Catherine Witczak

Docket No. : 706737.4003

the proximal end of the distal housing is attachable to the distal end of the proximal housing.

(original) The system of claim 10, wherein the distal housing further comprises:
 a sleeve configured to receive the needle guard and slide axially within the automatic injection system; and

a sleeve bias member configured to apply pressure proximally to the sleeve and to compress upon activation of the automatic injection system prior to depression of the plunger.

- 12. (original) The system of claim 11, wherein the sleeve comprises a detent that abuts the shield and prevents movement of the needle guard distally within the sleeve.
- 13. (original) The system of claim 11, wherein the sleeve is configured to receive the needle guard such that the orientation of the needle guard is maintained throughout the range of axial slide motion.
- 14. (original) The system of claim 11, further comprising a ring coupled with the distal housing and configured to abut the sleeve bias member and wherein the sleeve is slideably coupled with the ring and the ring sets the proximal and distal limits to slide movement of the sleeve.
- (original) The system of claim 11, wherein the sleeve is configured to encompass a circumference of the needle guard.
- 16. (original) The system of claim 10, further comprising a depth adjuster coupled with the distal end of the distal housing, wherein the depth adjuster is extendable from the distal end of the distal housing and is substantially fixable in an extended position.
- 17. (currently amended) The system of claim  $1\theta$ , wherein the drive system comprises:
- a driver releasably coupled with the activation system, axially movable within the automatic injection system between a retracted and an extended position and configured to contact the proximal end of the plunger; and

a drive bias member configured to apply pressure to the driver, wherein the pressure

Applicant : Lars Tommy Westbye, et al. Appl. No. : 10/626,218

appliable by the drive bias member is sufficient to depress the plunger and further wherein activation of the activation system releases the driver to allow depression of the plunger.

- 18. (original) The system of claim 17, wherein the automatic injection system is configured to house the needle guard with the shield in a retracted position and the plunger extended when the driver is in the retracted position.
- 19. (original) The system of claim 18, wherein the driver is configured to extend and depress the plunger and engage the release mechanism upon activation of the automatic injection system, when the needle guard and medical cartridge are housed within the automatic injection system.
- 20. (original) The system of claim 17, wherein the automatic injection system is configured to allow the shield to extend to the extended position upon detachment of the proximal and distal housings and after activation of the automatic injection system.
- 21. (original) The system of claim 17, wherein the pressure appliable by the drive bias member is sufficient to slide the medical cartridge axially towards the distal end of the automatic injection system and insert the needle into a recipient of the dose.
  - (original) The system of claim 17, wherein the drive bias member comprises:
     an inner bias member; and
- an outer bias member having a diameter greater than the inner bias member; and
  a coupling configured to abut a proximal end of the outer bias member and a distal end of
  the inner bias member and couple the inner bias member with the outer bias member such that
  the inner and outer bias member can cooperatively extend and compress.
- (original) The system of claim 17, wherein the activation system comprises a depressible button configured to release the driver when depressed.
- 24. (original) The system of claim 1, wherein the automatic injection system further comprises an indicator to indicate when the dose is substantially injected.

 Applicant
 :
 Lars Tommy Westbye, et al.

 Appl. No.
 :
 10/626,218

 Examiner
 :
 Catherine Witczak

 Docket No.
 :
 706737.4003

## 25. (currently amended) A medical injection system, comprising:

a needle guard configured to house a pre-filled medical cartridge comprising a proximal end and a needle located at a distal end:

an automatic injection system configured to house the medical cartridge and needle guard and configured to inject a dose from the medical cartridge upon activation of the injection system, wherein activation of the injection system causes the needle guard to extend to an extended position that substantially covers the needle.

wherein the needle guard is removable from the automatic injection system in the extended position after injection of the dose.

26. (original) The system of claim 25, wherein the needle guard comprises:

a cartridge housing configured to house and retain the medical cartridge, the housing having an open distal end through which the needle is allowed to extend, and an open proximal end from which a depressible plunger located on a distal end of the medical cartridge is allowed to extend:

a shield slideably coupled with the cartridge housing and configured to extend between a retracted position for exposing the needle and an extended position for substantially covering the needle:

a shield bias member configured to apply pressure to extend the shield distally; and a release mechanism configured to retain the shield in the retracted position and release the shield when engaged.

- (original) The system of claim 26, wherein the plunger comprises a contact portion configured to engage the release mechanism upon depression.
- 28. (original) The system of claim 25, wherein the needle guard comprises a plurality of cooperating detents for locking the needle guard in the extended position.
- (original) The system of claim 28, wherein the needle guard is removable from the automatic injection system in the locked extended position after injection of the dose.

Applicant : Lars Tommy Westbye, et al.

 Appl. No.
 :
 10/626,218

 Examiner
 :
 Catherine Witczak

 Docket No.
 :
 706737,4003

30. (original) The system of claim 25, wherein the automatic injection system comprises:

a drive system configured to depress a depressible plunger extending proximally from a proximal end of the medical cartridge upon activation, wherein the drive system comprises:

a driver axially movable between a retracted and an extended position within the automatic injection system and configured to contact the plunger; and

a drive bias member configured to apply pressure to the driver to move the driver from the retracted position to the extended position; and

an activation system configured to retain the driver in the retracted position and allow the driver to extend to the extended position upon activation.

31. (original) The system of claim 30, wherein the automatic injection system further comprises:

a distal housing having an open distal end from which the needle extends when the driver is in the extended position; and

a proximal housing coupled with the drive system and attachable to the distal housing.

(original) The system of claim 31, wherein the distal housing comprises:
 a sleeve configured to receive the needle guard and move axially within the distal housing; and

a sleeve bias member configured to apply pressure proximally to the sleeve and compress prior to depression of the plunger when the automatic injection system is activated.

## 33. (currently amended) A needle guard, comprising:

a cartridge housing coupled with a release mechanism and having a fingergrip-less outer surface, the cartridge housing configured to house a <u>pre-filled</u> medical cartridge comprising a needle located on a distal end, a plunger and a carrier configured to carry a dose;

the shield having an open proximal end and an open distal end and a fingergrip-less outer surface, the shield slideably coupled with the cartridge housing and a release mechanism and configured to extend between a retracted and an extended position that substantially covers the needle when the cartridge is housed in the cartridge housing; Applicant : Lars Tommy Westbye, et al.
Appl. No. : 10/626,218
Examiner : Catherine Witczak

Docket No. 706737.4003

the release mechanism configured to retain the shield in the retracted position and allow the shield to extend upon engagement of the release mechanism; and

a bias member in contact with the shield and the cartridge housing and configured to apply pressure distally to the shield to extend the shield;

wherein the needle guard is housable within an automatic injection system; and

wherein the needle guard is removable from the automatic injection system in the extended position after injection of the dose.

34. (currently amended) An automatic injection system, comprising: an activation system configured to activate the automatic injection system: a distal housing having an open proximal end and an open distal end:

a proximal housing having an open distal end and attachable to the proximal end of the distal housing, wherein the proximal and distal housing are configured to house a needle guard and a pre-filled medical cartridge having a needle on a distal end, a plunger on a proximal end and a carrier configured to carry a dose located therebetween, wherein the dose is injected from the distal end of the distal housing, and wherein the needle guard is removable from the automatic injection system after injection of the dose:

a sleeve configured to receive the needle guard and slide axially within the automatic injection system;

a sleeve bias member located in contact with the sleeve and the distal housing and configured to apply pressure proximally to the sleeve and to compress upon activation of the automatic injection system prior to depression of the plunger;

a drive system coupled with the proximal housing and configured to depress the plunger and engage the release mechanism when the automatic injection system is activated, the drive system comprising;

a driver releasably coupled with the activation system, axially movable within the proximal housing between a retracted and an extended position and configured to contact the proximal end of the plunger; and

Applicant : Lars Tommy Westbye, et al.
Appl. No. : 10/626,218
Examiner : Catherine Witczak

Examiner : Catherine Witczak Docket No. : 706737.4003

a drive bias member configured to apply pressure to the driver, wherein the pressure appliable by the drive bias member is sufficient to depress the plunger and further wherein activation of the activation system releases the driver to allow depression of the plunger.

35. (previously presented) A method of injecting a dose from a pre-filled medical cartridge having a needle located on a distal end and a plunger located on a proximal end, comprising:

activating an automatic injection system to inject a dose from a medical cartridge housed within the automatic injection system, wherein activation allows a plunger extending from the proximal end of the medical cartridge to be depressed and a shield located on a needle guard housing the medical cartridge to extend distally;

removing the needle guard from the activation system with the shield in an extended position substantially covering the needle.

- 36. (original) The method of claim 35, wherein depression of the plunger engages a release mechanism located on the needle guard, and wherein engagement of the release mechanism allows the shield to extend distally.
- 37. (original) The method of claim 35, wherein activation axially moves the medical cartridge distally within the injection system to allow exposure of the needle from an open distal end of the injection system prior to depression of the plunger.
- 38. (original) The method of claim 36, wherein activation releases a driver coupled with a drive bias member configured to apply pressure to the driver and axially move the driver distally within the injection system to depress the plunger.
- 39. (original) The method of claim 38, wherein the injection system comprises a distal housing and a proximal housing detachably coupled with one another.
- 40. (original) The method of claim 39, wherein removing the needle guard comprises detaching the distal and proximal housings prior to removing the needle guard.
  - 41. (original) The method of claim 40, wherein detaching the distal and proximal

Applicant : Lars Tommy Westbye, et al.
Appl. No. : 10/626,218

Evaminer : Cotherine Witerals

Examiner : Catherine Witczak
Docket No. : 706737.4003

housings comprises detaching the housings such that the shield extends to the extended position.

- 42. (original) The method of claim 41, wherein the needle guard further comprises a cartridge housing for housing the medical cartridge and wherein the needle guard is at least partially housed within the distal housing after detachment.
- 43. (original) The method of claim 42, wherein detaching the distal and proximal housings comprises detaching the housings such that the shield raises the cartridge housing proximally to facilitate removal of the cartridge housing from the distal housing.
  - 44. (original) The method of claim 39, further comprising:

inserting the needle guard into the distal housing with the shield in a retracted position maintained by the release mechanism:

moving the driver proximally within the proximal housing to a retracted position such that the driver releasably couples with an activation system; and

coupling the distal and proximal housing with one another prior to activating the automatic injection system.

- 45. (original) The method of claim 35, wherein the shield is substantially locked in the extended position to prevent inadvertent penetration with the needle.
- (original) The method of claim 35, wherein the depression of the plunger injects substantially the entire dose.
- 47. (original) The method of claim 35, wherein the plunger comprises a shaft with a proximal end, and a contact portion extending outward from the proximal end of the shaft, wherein the contact structure engages the release mechanism upon depression of the plunger.
- (original) The method of claim 38, wherein axial movement of the driver distally engages the release mechanism.